1.0 PURPOSE

The purpose of this policy is to provide guidance to research personnel about DAIDS requirements for documentation of the source of data collected during the conduct of clinical trials. Documentation of source data is necessary for the reconstruction, evaluation, and validation of clinical findings, observations, and other activities during a clinical trial.

2.0 SCOPE

This policy applies to data collected for all DAIDS funded and/or sponsored therapeutic, vaccine, or prevention clinical trials both domestic and internationally.

3.0 BACKGROUND

Source documentation serves to substantiate the integrity of trial data, confirm observations that are recorded, and confirm the existence of subjects. This policy also serves to ensure data quality by creating audit trails and enabling verification that data are present, complete, and accurate. In multi-site clinical trials it is important for documentation of source data to be standardized across all sites to ensure consistency of the trial data. This policy is based upon: 1) the Code of Federal Regulations (CFR), 2) FDA, OHRP and NIH guidance applicable to the involvement and protection of human subjects in clinical research, and 3) standards for good clinical practice (GCP).

4.0 DEFINITIONS

Source Data – All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents – Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

For additional definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

DAIDS is responsible for maintaining detailed documentation standards for all of its sponsored and/or funded clinical trials. It is the responsibility of DAIDS program staff to assist and provide guidance to grantees and site staff regarding recordkeeping and retention, as appropriate.

The Principal Investigator is responsible for ensuring the clinical research site staff are trained in GCP to include record retention and that clinical sites with studies sponsored or funded by DAIDS adhere to this policy.

It is the responsibility of the Clinical Research Site investigators and staff to maintain records consistent with this policy, and federal, state and local regulations as applicable.

6.0 POLICY

- All data must be verifiable from the written source documentation that meets DAIDS standards.

- Source Documentation Requirements for DAIDS sponsored and/or funded clinical trials are updated as necessary and available in Appendix 1 and on the NIAID website " DAIDS Clinical Research Policies and Standard Procedures."

- Local, state, institution, institutional review board (IRB)/independent ethics committee (IEC) policies and procedures must be followed if they are more stringent than the DAIDS Policy.

- The **"ALCOA"*** method should be applied to help achieve and maintain data quality:

  1. **A**ttributable: is it obvious who wrote it?
  2. **L**egible: can it be read?
  3. **C**ontemporaneous: is the information current and in the correct time frame?
  4. **O**riginal: is it a copy; has it been altered?
  5. **A**ccurate: are conflicting data recorded elsewhere?

*Source: The facts About Source Documents" by Stan W. Woollen, Presented at the 1999 DIA Annual Meeting

7.0 REFERENCES

U.S. Code of Federal Regulations 45 CFR 46, 45 CFR 46 Subpart D,

U.S. Code of Federal Regulations 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 11

International Conference on Harmonisation Guidance: E6 Good Clinical Practice (GCP)

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:

NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm

The signed original is maintained in the OPCRO policy office.

10.0 CHANGE SUMMARY

Version #	Date	Replaces	Date of Revision	Rationale for Revision/Retirement
1.0	14 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

Appendix 1 - DAIDS Source Documentation Requirements

12.0 APPROVAL

	Signature	Program/Branch	Date
Authorized By:	Richard Hafner Richard Hafner, MD Director	Office for Policy in Clinical Research Operations	July 14, 2006